

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 54084-51433	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2004/038176	International filing date (<i>day/month/year</i>) 15 November 2004 (15.11.2004)	Priority date (<i>day/month/year</i>) 13 November 2003 (13.11.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant SYNERGETICS, INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 15 May 2006 (15.05.2006) Authorized officer <p style="text-align: center; font-weight: bold;">Agnes Wittmann-Regis</p> Telephone No. +41 22 338 89 70
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 30 SEP 2005

PCT WIPO PCT

To:
JOSEPH M. ROLNICKI
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ST. LOUIS, MO 63101

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 28 SEP 2005	
Applicant's or agent's file reference 54084-51433	
FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US04/38176	International filing date (day/month/year) 15 November 2004 (15.11.2004)
Priority date (day/month/year) 13 November 2003 (13.11.2003)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 18/18 and US Cl.: 606/015	
Applicant SYNERGETICS, INC.	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application


2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Ahmed M. Farah Telephone No. (703) 305-3590 <div style="text-align: right;">  Sheila H. Venev Paralegal Specialist Tech. Center 3700 </div>
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/38176

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/38176

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-16</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-16</u>	NO
Industrial applicability (IA)	Claims <u>1-16</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-16 lack an inventive step under PCT Article 33(3) as being obvious over Claims 1-16 lack an inventive step under PCT Article 33(3) as being obvious over Murphy-Chutorian et al. U.S. Patent No. 5,855,577 in view of Esch et al. U.S. Patent No. Re.36,473.

Murphy-Chutorian et al. disclose catheter apparatus and method of use, the catheter comprising:

an instrument handle 128;

a tubular sleeve (catheter shaft 102) projecting from the instrument handle;

an optical fiber 120 extending through the handle and the sleeve to a distal end portion that projects from the sleeve, the distal end portion 118 of the optic fiber 120 having an adjustable bend therein (see Fig. 4);

a handle mechanism that 144 that is connected to both the sleeve and the optical fiber 120, which selectively moves the optical fiber between pushed forward and pulled-back positions relative to the handle 128 and the sleeve; and

the tubular sleeve (catheter shaft 102) is a semi-rigid tube that projects from the handle 128, the distal end portion of the optical fiber 118 has a preformed bend that is straightened when the optical fiber is retracted into the sleeve and the preformed bend bends when the optical fiber is moved to the pushed forward position (see Figs. 2 and 4, and Col. 8, lines 43-51).

An air gap inherently exists between the sleeve interior surface and the optical fiber in the sleeve in order to allow the optical fiber to move within the sleeve.

The tubular sleeve has an anterior surface and a layer of sliding material (guide wire 122) between the interior surface of the sleeve and the optical in the sleeve. See Fig. 2, Col. 7, lines 19-20, and claim 12.

However, although Murphy-Chutorian et al. use a stainless steel wire integrated within the sleeve, they do not teach that the use of rigid tube.

Esch et al. teach an alternative treatment device comprising a handle 37; a semi-rigid tubular shaft 43; a sliding mechanism 41, and an energy delivery optical fiber 53 disposed within the slidable sleeve (see Figs. 3 and 5). They further teach that it is desirable to use a semi-rigid wire to reinforce the device if piercing of a body tissue is needed.

Therefore, it would have been obvious to one skilled in the art at the time of the applicants' invention to modify Murphy-Chutorian et al. in view of Esch et al. and use a rigid or a semi-rigid element in order to reinforce the tube if piercing of the tissue is required.

Claims 1-16 meet the criteria under PCT Article 33(4), because the subject matter claimed can be made or used in industry.